DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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VIA Federal Express

WARNING LETTER CIN-24764

February 16, 2005

Mr. Vernon H. Merritt, President/CEO
Icon Interventional Systems, Inc.
1414 South Green Road, Suite 309
South Euclid, OH 44121

Dear Mr. Merritt:

On 12/16-29/2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located in South Euclid, OH. The inspection was conducted to determine your firm's compliance with the Import for Export provision of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 381(d)(3).

Under this provision of the Act, importers wishing to import violative products that are intended for further processing must provide FDA with notification, at the time of initial importation, that the products are intended to be incorporated or "further processed" by the initial owner or consignee, into products that will be exported. Among other things, the initial owner or consignee of the article also must maintain records of the use and/or destruction of such imported articles or portions thereof.

Our inspection revealed that on 10/23/2004, you imported [redacted] angioplasty catheters of various sizes. These are Class III catheters for which you do not have Pre-market Approval. These articles are devices within the meaning of 21 U.S.C. § 321(h), which may not be introduced or delivered for introduction into interstate commerce under 21 U.S.C. § 351(f)(1), without such approval.

At the time of importation you provided an "import for export" notification for these catheters. Information regarding the "import for export" nature of this entry of catheters was submitted to the FDA through your broker DHL Express, and was printed on the commercial invoice for the shipment.

Our investigation further revealed that out of the [redacted] catheters, 79 catheters were manufactured into stent systems, and used in engineering and animal studies. They were not exported or destroyed as required by the Act.

The above identified violations are not intended to be all inclusive of the violations noted at your facility. It is your responsibility, as the importer of record, to assure that your establishment is in compliance with federal law.

You should take prompt measures to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We have received your letter dated January 27, 2005, and although it appears from your response that you are working toward correcting the violations noted at your firm, you must implement and maintain each corrective action to ensure its effectiveness. We are in the process of reviewing your January letter and later submissions and await the finalization of your evaluation of your catheter import entries, as noted on page 4 of your January letter.

FDA will respond to your submissions once they are complete. Please notify this office, in writing, within 15 working days of receipt of this letter, and of any additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

Your written reply relating to these concerns should be addressed to: Stephen J. Rabe, Compliance Officer at the address noted in the letterhead above.

Sincerely,

Carol A. Heppe
District Director, Cincinnati District
Food and Drug Administration